IN THE UNITED STATES DISTRICT COURT
FOR THE NORTERN DISTRICT OF ILLINOIS
EASTERN DIVISION

LINDA HOBBS, individually and as a representative of the class, Plaintiff, vs. GERBER PRODUCTS CO., a corporation, d/b/a NESTLE NUTRITION, NESTLE INFANT NUTRITION, AND NESTLE NUTRITION NORTH AMERICA, Defendant.	Case No.: **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

1. Plaintiff Linda Hobbs ("Plaintiff"), on behalf of herself and all other persons who purchased Gerber Good Start Gentle infant formula in Illinois, alleges as follows on personal knowledge concerning all facts related to herself, and on information and belief concerning all other matters:

NATURE OF THE ACTION

2. This case involves a pattern of deceit and unfair business practices by Gerber Products Co. ("Defendant" or "Gerber") in the marketing and sale of Good Start Gentle, a prominent line of infant formula produced by Defendant made from partially hydrolyzed whey protein.

3. Plaintiff brings this class action lawsuit challenging false representations and misleading practices knowingly made or undertaken by Defendant in Good Start Gentle's promotional campaign including: (a) that Good Start Gentle was the "first and only" formula whose consumption reduced the risk of infants developing allergies; (b) that consumption of

Good Start Gentle reduced the risk of developing infant atopic dermatitis, an inflammatory skin disorder commonly known as eczema; (c) that Good Start Gentle was the "first and only" formula endorsed by the Food and Drug Administration ("FDA") to reduce the risk of developing allergies; and (d) using the FDA term of art "Qualified Health Claim" to convey Good Start Gentle received FDA approval for the health claims advertised and was fit for a particular purpose when, in actuality, the term "Qualified Health Claim" means the FDA did not grant approval for the use of a unqualified health claim and the scientific support for the claim is limited or lacking (at best).

4. This is not the first time that Gerber's corporate parent—Nestle—has made false and misleading statements to consumers about the purported allergic benefits of Good Start Gentle. Starting in the late 1980s, Nestle began manufacturing, promoting, and selling partially hydrolyzed whey protein infant formulas under the Carnation (another U.S. company that Nestle acquired) Good Start brand name. Nestle promoted Carnation Good Start formulas as being "hypoallergenic" but was forced to stop making the claim after the FDA began questioning its scientific support. Nestle was also fined by nine states for falsely and misleading claiming in its advertisements that Good Start was unlikely to trigger allergies.

5. In 2005, Nestle—through a subsidiary Nestle USA, Inc. ("Nestle USA")—petitioned the FDA to approve a qualified health claim linking partially hydrolyzed whey protein with a reduced the risk of infants developing food allergies. In 2006, based on its review of the publicly available scientific evidence, the FDA rejected Nestle's proposed health claim, stating that "no credible evidence" supported a connection between consuming partially hydrolyzed whey protein and a reduced risk of food allergies. The FDA further rejected the use of a "disclaimer or qualifying language to accompany" Nestle's proposed claim, stating "neither a

disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance, where there is no credible evidence to support the claim."

6. In 2007, Nestle acquired infant food manufacturer Gerber. Gerber did not manufacture or sell infant formula at the time, but Good Start Carnation was eventually rebranded under the Gerber banner.

7. In 2009, Defendant petitioned the FDA to approve a qualified health claim linking partially hydrolyzed whey protein to a reduced risk of infants developing atopic dermatitis. In 2011, based on its review of the publicly available scientific evidence, the FDA rejected the health claim language proposed by Defendant because it mischaracterized the "strength of the evidence" and would "mislead consumers." Instead, the FDA stated that it would only consider exercising its enforcement discretion regarding the atopic dermatitis claim if Defendant modified the claim and included highly qualifying language that very little or little scientific evidence (depending on infant age) existed to support the link.

8. However, beginning in at least 2011, despite the FDA's clear rejections and compelling evidence contradicting its claims, Defendant falsely advertised Good Start Gentle as the first and only infant formula to reduce the occurrence of allergies generally, as well as the first and only infant formula endorsed by the FDA. Defendant made those claims in order to strategically outpace competitors and substantially increase its sales. Defendant undertook its marketing campaign with actual knowledge that its claims were false and misleading and disregarded the limitations imposed on it by the FDA.

9. Due to Defendant's pervasive and false marketing campaign that Good Start Gentle provided benefits to children's health beyond that offered by other baby formulas and that the FDA had certified that claim, Plaintiff and the other Class members (as defined below)

purchased Good Start Gentle at an inflated cost.

10. Plaintiff and the Class were injured by Defendant's unlawful conduct and are entitled to actual, statutory, and punitive damages, restitution, interest, and the reimbursement of attorneys' fees.

11. In October 2014, the Federal Trade Commission ("FTC") brought suit against Defendant seeking to enjoin its deceptive practices in relation to the marketing and sale of Good Start Gentle, specifically citing Defendant's false or unsubstantiated claim "that feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies," along with the false or misleading claim "that Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration."

12. Also in October 2014, the FDA issued Defendant a warning letter listing numerous misrepresentations and falsehoods Defendant made during the promotional campaign of Good Start Gentle that violated federal law and related regulations. Among other things, the FDA noted Good Start Gentle was misbranded and in violation of the Federal Food, Drug, and Cosmetic Act because Good Start Gentle labeling and Defendant's website were misleading. Defendant was instructed by the FDA to correct the violations or face potential legal action.

13. Plaintiff, on behalf of herself and other similarly situated consumers, brings this consumer protection action against Defendant based on its course of unlawful conduct. Plaintiff alleges violations of Illinois Consumer Fraud and Deceptive Trade Practices Act, as well as Breach of Express Warranty, and Intentional Misrepresentation.

PARTIES

14. Plaintiff is and was at all relevant times herein, a resident of Illinois and is a

member of the Class. Plaintiff frequently purchased Gerber Good Start Gentle infant formula based on Defendant's false advertising and deceptive business practices.

15. Defendant, also doing business as Nestle Nutrition, Nestle Infant Nutrition, and Nestle Nutrition North America, is a Michigan corporation with its headquarters located in Florham Park, New Jersey. Throughout the Class Period (as defined below), Defendant has transacted business in this district and throughout Illinois, including marketing, distributing, and selling Good Start Gentle.

JURISDICTION AND VENUE

16. This Court has original jurisdiction over this case under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). Plaintiff is a citizen of Illinois and Defendant is a citizen, for diversity purposes, of New Jersey and Michigan. The amount in controversy in this action exceeds $5,000,000 and there are more than 100 members in the Class.

17. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct business in Illinois, is doing business in Illinois, is registered with the Illinois Secretary of State, and maintains a registered agent in Springfield, Illinois. Alternatively, Defendant is engaged in systematic and continuous business activity in Illinois, has sufficient minimum contacts in Illinois, or otherwise intentionally avails itself of the Illinois consumer market through the promotion, marketing, distribution, and sale of consumer goods, including Good Start Gentle. This purposeful availment renders the exercise of jurisdiction by this Court over Defendant appropriate under traditional notions of fair play and substantial justice.

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Defendant regularly conducts business in this District, and Defendant is subject to personal jurisdiction in this District.

19. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Defendant's History of Falsely Promoting the Allergic Benefits of Good Start

20. Nestle, Gerber's parent, has a long and checkered history of manufacturing, selling, promoting, and marketing Good Start and other infant formulas in the Unites States and around the world. There have been numerous boycotts related to Nestle's direct to consumer sales and marketing practices in countries outside the United States. These practices and the attendant boycotts led, in part, to the World Health Organization's adopting the International Code of Marketing Breast-Milk Substitutes (the "WHO Code"), which banned direct to consumer advertising in those countries that adopted the Code. While the United States has not adopted the WHO Code, there was—into the late 1980s—a voluntary ban on such advertising.

21. Though Nestle was a major supplier of infant formula worldwide, Nestle did not sell infant formula in the United States until the late 1980s. Nestle had acquired Carnation in 1984, and in 1988 announced that it would enter the United States infant formula market by promoting its Good Start Formula (which it was already manufacturing and selling in Europe) to consumers in the United States under the banner of the Carnation brand. Nestle expected its formula to capture 25-30% of the infant formula market in the United States within a few years of its introduction. Denise Gellene, *Carnation to Move Into U.S. Baby Formula Market, L.A. Times*, June 4, 1988, *available at* http://articles.latimes.com/1988-06-04/business/fi-3994_1_infant-formula-market (last visited May 9, 2017).

22. The announcement of Nestle's plans to market the formula directly to consumers created an uproar in the pediatric community, including the American Academy of Pediatrics. As

the Los Angeles Times reported on July 2, 1988, in an article entitled "*Marketing to Moms: Pediatricians Say Carnation Crosses a Fine Ethical Line in Direct Sales of Baby Formula*"—

> Carnation, which is owned by the Swiss company, Nestle, has unveiled plans to introduce a formula—called Good Start—for infants who are allergic to traditional milk and soybean-based formulas. Good Start and Good Nature, a formula for infants who have begun to eat solid foods, will be advertised in magazines that are read by new mothers—a break with the voluntary ban on such ads.

Jesus Sanchez, *Marketing to Moms: Pediatricians Say Carnation Crosses a Fine Ethical Line in Direct Sales of Baby Formula*, L.A. Times, July 2, 1988, *available at* http://articles.latimes.com/1988-07-02/business/fi-5340_1_baby-formula (last visited May 9, 2017).

23. Nestle eventually resolved its dispute with the American Academy of Pediatrics "by agreeing not to link Carnation's name to a public information campaign on allergic reactions to infant formula." George White, *Carnation Says It Has Settled Dispute on Ads: Pediatrics Group Hit Campaign on Formulas*, L.A. Times, July 15, 1988, *available at* http://articles.latimes.com/1988-07-15/business/fi-7239_1_ad-campaign (last visited May 9, 2017).

24. Nestle violated the spirit of this agreement, however, by promoting Good Start's purported hypoallergenic properties on its label. On March 11, 1989, the Los Angeles Times reported that, following a request from the FDA for more information on its purported allergy claims, "Carnation Co., under fire for using an infant formula label that has been called misleading, on Friday said it will remove the term 'hypo-allergenic' from its Good Start H.A. product. Carnation said the label change, which will be effective in April, is being made to eliminate potential consumer confusion . . . ." George White, *Carnation to Alter Label on Baby*

Formula, L.A. Times, March 11, 1989, *available at* http://articles.latimes.com/1989-03-11/business/fi-773_1_infant-formula-label (last visited May 9, 2017).

25. After agreeing to remove the term "hypoallergenic" from the Good Start label, Carnation also agreed to pay fines to nine states over claims that "it used misleading advertising to promote its new infant formula as unlikely to trigger allergies." Jesus Sanchez, *Carnation to pay $90,000 fine in wake of claims its ads misled Los Angeles Times*, L.A. Times, July 7, 1989, *available at* http://articles.latimes.com/1989-07-07/business/fi-3433_1_health-claims (last visited May 9, 2017).

26. By 1990, Nestle failed to gain the 25–30% share that it had projected. As Carnation's promotional efforts for Good Start floundered, on December 31, 1990, the Los Angeles Times reported that Carnation decided to reverse course on direct-to-consumer advertising and, "over the objections of pediatricians and advocates of breast feeding, will begin advertising its Good Start formula directly to mothers, beginning in January." Jesus Sanchez, *Nestle's New Accent*, L.A. Times, Dec. 31, 1990, *available at* http://articles.latimes.com/1990-12-31/business/fi-5671_1_food-industry (last visited May 9, 2017).

27. But even after reviving its plan to advertise directly to consumers, Nestle was unable to capture its desired U.S. market share, which remained below 5%. Nestle eventually blamed this on a conspiracy between doctors and dominant formula makers to prevent direct-to-consumer advertising, and brought an antitrust action against these parties in 1993.

28. On June 21, 1995, jurors rejected Nestle's antitrust case. Thereafter, the Ninth Circuit rejected Nestle's appeal, affirming the district court's determination. *See Nestle Food Co. v. Abbott Labs, et al*, 105 F.3d 665 (9th Cir. 1997).

29. After losing in court, Nestle continued promoting Good Start directly to

consumers. Nestle also looked to again promote the purported allergenic health benefits of its Good Start formula. As part of that strategy, and as described more fully below, in June 2005 Nestle petitioned the FDA for approval of a qualified health claim that Good Start can reduce the risk of common food-allergy symptoms. The FDA rejected that claim in May 2006, finding that there was "no credible evidence" to support it.

30. Following the FDA's denial of its Good Start allergy claims, in 2007 Nestle acquired Gerber, which at the time was a leading manufacturer and seller of infant food but did not manufacture or sell infant formula. In a slide presentation announcing the acquisition, dated April 12, 2007, Nestle touted that one important feature of the acquisition would be to allow Nestle to "Leverag[e] the trust and well-being reputation of the Gerber brand." At some point following Gerber's acquisition, Nestle rebranded "Good Start" as "Gerber Good Start."

31. Thereafter, and since at least 2011, Defendant has manufactured, distributed, promoted, offered for sale, and sold Good Start Gentle infant formula. Defendant has advertised and continues to advertise Good Start Gentle formula through television commercials, print advertisements, point-of-sale displays, product packaging, internet advertisements, and other promotional materials.

B. Federal Law Requires FDA Approval Before Companies Can Make A Legal "Health Claim"

32. Under federal law, the FDA is the governmental body tasked with reviewing and authorizing health claims relating to food products sold in the United States. *See* FDA, *Questions and Answers: Qualified Health Claims in Food Labeling* (Sept. 28, 2005), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm (last visited May 9, 2017).

33. A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health related condition. An example of a health claim is: "Diets low in saturated fat and cholesterol may reduce the risk of heart disease." *Id.*

34. Health claims fall into two categories. An "unqualified health claim" must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. A "qualified health claim," on the other hand, is supported by scientific evidence, but does not meet the significant scientific agreement standard. As such, to ensure that the health claims are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language accurately communicating the level of scientific evidence supporting the claim. *Id.*

35. All health claims, whether qualified or unqualified, require pre-market review by the FDA. The FDA authorizes by regulation unqualified health claims on product labels only if the substance/disease relationship described by the health claims meets the "significant scientific agreement" standard. For approved qualified health claims, the FDA issues letters of enforcement discretion when there is credible evidence to support the claim. *Id.* Qualified health claims must include disclaimers that remedy any potential harm caused by potentially misleading claims. *Id.*

C. The FDA Denies Nestle's Petition for a Qualified Health Claim Linking Partially Hydrolyzed Whey Protein with a Reduction of Common Food Allergies in 2006

36. Gerber Good Start Gentle is made with partially hydrolyzed whey protein. Whey protein is derived from cow's milk during the production of cheese. Partially hydrolyzed whey

protein undergoes additional processing with heat and enzymes to break the protein into smaller fragments.

37. In June 2005, Nestle, through Nestle USA, petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow's milk formula from the initiation of formula feeding.

See Qualified Health Claims: Letters of Denial – 100 Percent Partially Hydrolyzed Whey Protein in Infant Formula and Reduced Risk of Food Allergy in Infants (Docket No. 2005Q-0298) (May 11, 2006), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm (last visited May 9, 2017).

38. The FDA found that no scientific or other evidence supported Nestle's health claim linking the consumption of partially hydrolyzed whey protein with a reduced risk of infants developing food allergies. In particular, the FDA reviewed thirty-six studies evaluating the relationship and concluded that none drew a sound scientific conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk. *Id.* at Appendix 1 (The studies suffer from a multitude of deficiencies, including improper controls and unacceptable diagnoses of food allergies.).

39. On May 11, 2006, after "its review of the totality of publicly available scientific evidence, [the] FDA conclude[d] that there is no credible evidence for a relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced

risk of food allergy." *Id.* After so concluding, the FDA denied Nestle's qualified health claim petition. *Id.* Critically, the FDA determined that "neither a disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance." *Id.*

40. The FDA's denial letter was addressed to Melanie Fairchild-Dzanis, Nestle USA's Director of Regulatory Issues—Special Nutritional. Fairchild-Dzanis is a lawyer and managed Nestle USA's regulatory function at that time.

41. As a result of its dealing with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infant allergies was baseless, false and incurable with qualifiers, and (b) the FDA rejected its qualified health claim regarding the link.

D. The FDA Rejected Defendant's Petition for a Health Claim Linking Partially Hydrolyzed Whey Protein and a Reduced Risk of Atopic Dermatitis in Infants As Proposed in 2011

42. In May 2009, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research shows that, in healthy infants with family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula instead of a formula containing intact cow's milk proteins may reduce the risk of developing the most common allergic disease of infancy—atopic dermatitis—throughout the 1st year of life and up to 3 years of age.

See Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (May 24, 2011), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm (last visited May 9, 2017).

43. In May 2011, after reviewing the totality of publicly available scientific evidence at the time, the FDA made two findings regarding Gerber's qualified health claim. *Id.* First, the FDA concluded that there "is very little credible evidence for a qualified health claim about the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and a reduced risk of atopic dermatitis throughout the first year of life and up to 3 years of age." *Id.* Second, the FDA concluded "that there is little credible evidence for a qualified health claim about the relationship between feeding 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced risk of atopic dermatitis throughout the first year of life." *Id.*

44. As a result, the FDA rejected Defendant's claim as proposed because it "mischaracterized the strength of the evidence and [was] misleading." *Id.*

45. The FDA stated that it would only consider exercising its enforcement discretion regarding Defendant's atopic dermatitis claim if Defendant attached qualifying language to the effect that "very little scientific evidence" or "little scientific evidence" supports the link between partially hydrolyzed whey protein and a reduced risk of atopic dermatitis depending on the infant age included in the claim. *Id.* The FDA also required Defendant to include stringent language warning parents and other caretakers that "**Partially hydrolyzed formulas should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms.**" *Id* (emphasis in original).

46. The FDA's 2011 denial letter was similarly addressed to Ms. Fairchild-Dzanis.

47. As a result of its dealings with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infants developing atopic dermatitis was false or supported by little or very little scientific evidence (at best at the

time) and (b) the FDA rejected Defendant's qualified health claim regarding the link as proposed because the claim was misleading and required that if Defendant was to make the claim it do so with rigorous qualifying statements.

E. Compelling Scientific Studies Conclude That Partially Hydrolyzed Whey Formula Does Not Lower The Risk of Allergic Manifestations (Including Eczema) In Infancy When Compared With Conventional Formula

48. Defendant's claims linking the consumption of Good Start Gentle (a formula made with partially hydrolyzed whey protein) with a reduced risk of developing allergies and atopic dermatitis (a form of eczema) are false and misleading.

49. Several compelling scientific studies have concluded that partially hydrolyzed whey formula does not lower the risk of developing allergies or allergic manifestations, including eczema, during infancy (and up to age 7) when compared with conventional formula.

50. One such study published in June 2011 concluded that "[t]here was no evidence that introducing [partially hydrolyzed whey formula] at the cessation of breast-feeding reduced the risk of allergic manifestations, including eczema, asthma, and allergic rhinitis, in [a] study of high-risk infants." Adrian J. Lowe, PhD et al., *Effect of a partially hydrolyzed whey infant formula at weaning on risk of allergic disease in high-risk children: A randomized controlled trial*, 128 J. ALLERGY & CLIN. IMMUNOL. 2, Aug. 2011, at 360-65.e4 ("Lowe Study"), attached hereto as **Exhibit A**.

51. The Lowe Study further concluded that partially hydrolyzed whey formula did not reduce the risk of allergic manifestations, including eczema, (1) in children from birth to age 7 and (2) in children both with and without a family history of eczema when compared with conventional formula. *Id.* Moreover, there was "no evidence of reduced risk of skin prick test

reactivity" to six common allergens, including cow's milk, egg white, peanut, house dust mite, rye grass, and cat dander. *Id.*

52. The Lowe Study did "not support the recommendation that [partially hydrolyzed whey formula] should be used after breast-feeding as a preventative strategy for infants at high risk of allergic diseases." *Id.* The Lowe study is particularly notable because it was the "second largest trial to randomize individual infants to receive either [partially hydrolyzed whey protein] or conventional cow's milk formula."

53. Upon information and belief, Defendant knew or should have known about the Lowe Study's rejection of its health claims because Nestec Ltd, a subsidiary of Nestle Australia Ltd, provided the Lowe Study with study formula and staff funding for the first 6 years of the study. *Id.* Upon information and belief, Nestec Ltd and Nestle Australia Ltd are affiliated with Defendant. *See* Nestle S.A., Annual Report 2013 at 154, 165, 170, *available at* http://www.nestle.com/asset-library/documents/library/documents/annual_reports/2013-annual-report-en.pdf (last visited May 9, 2017).

F. Defendant Widely Markets Good Start Gentle as the First and Only Infant Formula Endorsed by the FDA Which Prevents Allergies and Reduces the Risk of Atopic Dermatitis

54. Despite the FDA's express guidance and compelling evidence contradicting Defendant's claims, Defendant falsely marketed Good Start Gentle as a product endorsed by the FDA for reducing the risk of developing allergies and atopic dermatitis to attract customers, increase revenues, and edge out Defendant's competition.

55. Since at least 2011, Defendant knowingly disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Good Start Gentle in

Illinois containing false and misleading statements, as demonstrated by the following sample of Good Start Gentle promotional materials.

56. In **Exhibit B**, a tamper-evident seal attached to plastic formula containers of Good Start Gentle from July 2013 until January 2015, Defendant prominently states that Good Start Gentle is the "1st and ONLY Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES." Exhibit B falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing all allergies despite the total lack of evidence supporting that proposition, an FDA letter rejecting Defendant's qualified health claim, and compelling evidence, such as the Lowe Study, contradicting the claim.

57. In **Exhibit C**, a coupon, a gold badge with the words "Meets FDA" printed at the top, "1st and Only" printed in the center, and "Qualified Health Claim" printed at the bottom. The coupon further includes a statement that Good Start Gentle "is the first and only formula brand . . . that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis." Exhibit C falsely communicates to consumers that the FDA approved Defendant's qualified health claim regarding atopic dermatitis when the FDA, in fact, rejected the claim as proposed because it misled consumers. It also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. The coupon notably fails to include the qualifying language required by the FDA and federal law.

58. In **Exhibit D** (a storyboard dated April 9, 2012), a television commercial, an announcer states that "You want your Gerber baby to have your imagination . . . your smile . . . your eyes . . . not your allergies. . . . [I]f you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage." (emphasis added). *See* Gerber Good Gentle Formula with

Comfort Proteins Advantage Commercial, https://www.youtube.com/watch?v=h6l-CjygjEg (last visited May 9, 2017). This advertisement falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite compelling evidence contradicting that proposition and an FDA letter rejecting Defendant's 2005 qualified health claim petition.

59. In **Exhibit E**, a print advertisement depicting a baby's face on a canister of Good Start Gentle, the caption reads, "I love Mommy's eyes, not her allergies. If you have allergies in your family, breastfeeding your baby can help reduce their risk. And if you decide to introduce formula research shows the formula you first provide to your baby may make a difference." (emphasis added). Exhibit E falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite compelling evidence contradicting that representation and an FDA letter rejecting Defendant's qualified health claim. The advertisement also notably fails to include the qualifying language required by the FDA and federal law.

60. In **Exhibit F**, a magazine advertisement, Defendant promoted Good Start Gentle as "the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

61. In **Exhibit G**, a magazine advertisement printed in People Magazine on August 5, 2013, a mother is depicted feeding an infant and a badge is included which states that Good Start

Gentle is the "1st Formula with FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

62. During the Class Period, in addition to this sample, Defendant disseminated numerous other advertisements and promotional materials touting Good Start Gentle's ability to reduce the risk of developing allergies, atopic dermatitis, as well as misleadingly using the FDA term of art "qualified health claim."

63. Reasonable consumers, including Plaintiff, attached importance to Defendant's health and FDA approval claims when determining whether to purchase Gerber Good Start. For example, parents and caretakers, like Plaintiff, are concerned with the health of their children, and their decision to purchase (or pay a premium for) a formula would be influenced by claims that: partially hydrolyzed whey protein reduces the risk of allergies, and the FDA unequivocally endorsed the health claims Defendant made on its labels, in its advertisements, and on its website.

64. Defendant's misrepresentations were material, increased sales, and allowed Gerber to inflate the price of Good Start Gentle beyond what it would otherwise be able to charge consumers.

G. The FTC Sues Defendant Seeking A Permanent Injunction and Other Equitable Relief for Violations of the Federal Trade Commission Act Committed During u Defendant's Promotional Campaign for Good Start Gentle

65. On October 29, 2014, the FTC filed a lawsuit in the District of New Jersey against Defendant "under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) to obtain preliminary and permanent injunctive relief . . . for Defendant's acts or practices, in violation of Section 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies." *Federal Trade Commission v. Gerber Products Co.*, 2:14-cv-06771-SRC-CLW, Dkt. No. 1, at 1 (D.N.J. Oct. 29, 2014).

66. In its complaint, the FTC specifically challenged Defendant's false and unsubstantiated claim that "feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and Gerber's false assertions that "Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration." *Id.* at 9-10.

H. The FDA Issues a Warning Letter to Defendant Stating that Good Start Gentle is Misbranded and Misleading in Violation of Federal Law

67. In addition to the lawsuit filed by the FTC on October 29, 2014, on October 31, 2014, the FDA wrote a warning letter addressed to Mr. Gary Tickle, Defendant's President and CEO, outlining various false and misleading representations made in the promotion of Good Start Gentle that violate federal law and related federal regulations. *See generally* Warning Letter, Nestle Infant Nutrition 10/31/14,

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.htm (last visited May 9, 2017) ("Warning Letter").

68. The violations cited by the FDA include that:

a) Good Start Gentle was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, because Good Start Gentle's labeling and website "bear health claims that were not authorized by the FDA." *See* Warning Letter at 2;

b) Good Start Gentle was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, because Good Start Gentle's labeling, specifically the tamper evident seal shown in Exhibit B, was "misleading." *See id*;

c) Defendant's health claim that the consumption of 100% partially hydrolyzed whey protein reduces the risk of infants developing food allergies was a health claim previously considered and denied by the FDA and therefore unauthorized. *See* Warning Letter at 2-3;

d) Defendant failed to ensure safety by not properly informing consumers that Good Start Gentle should not be fed to infants with milk allergies and that such infants' "care and feeding choices should be under a doctor's supervision." *See* Warning Letter at 2-4 (Defendant omitted to include key information in mandatory bold type and excluded other mandatory language entirely.);

e) Good Start Gentle is misbranded because Defendant wrongly identified "100% whey partially hydrolyzed" as the substance linked to a reduced risk of atopic dermatitis on Good Start Gentle's label and website. *See* Warning Letter at 3. However, the substance that was the subject of Defendant's 2011 qualified health claim petition to the FDA was "100% whey protein partially hydrolyzed." *Id.* As such, Defendant's health claim regarding atopic dermatitis misleads consumers because it suggests "that the partial hydrolysis of whey could refer to any or all of the components in whey being hydrolyzed (*i.e.*, oligosaccharides, fats, and protein)," and no evidence exists to support such claim. *See* Warning Letter;

f) Defendant separated qualifying language related to its atopic dermatitis health claim on its website in a way not approved by the FDA in its 2011 letter of enforcement discretion to Defendant. *See* Warning Letter at 5. The FDA expressed concerns that such separation could mislead consumers.

69. In the letter, the FDA instructed Defendant to "take prompt action to correct the violations described above" or face potential legal action. *See* Warning Letter at 5.

70. In a letter dated November 19, 2014 to the FDA, Mr. Tickle discussed the corrective actions Defendant was taking in response to the FDA's Warning Letter. Among other things, Mr. Tickle discussed the use of the tamper-evident seal shown in **Exhibit B**, stating specifically "We have revisited the issue following receipt of the [Warning] Letter and have made the decision to discontinue the sticker" beginning in January 2015.

71. On July 13, 2015, the FDA issued a "Close Out Letter" to Defendant. In the Close Out Letter, the FDA described its evaluation of Defendant's corrective actions and stated "it appears that you have addressed the violations" contained in the Warning Letter. *See* Close Out Letter, Nestle Infant Nutrition 7/13/15, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm454778.htm (last visited May 9, 2017).

72. Based upon information and belief, the FDA is no longer actively investigating Defendant's false and misleading marketing of Good Start Gentle.

I. Plaintiff Begins Consistently Purchasing Good Start Gentle Based on Defendant's False Promotional Campaign and Suffers Damages

73. During the Class Period, Plaintiff acted as a babysitter and caretaker to a number of nieces and nephews. Plaintiff's nephew Aniko, was born in May 2012; her nephew, Aaron, was born in September 2012; and her niece, Brooklyn, was born in April 2013. Plaintiff frequently babysat Aniko, Aaron, and Brooklyn during their infancy and was responsible for choosing and buying the infant formula they were fed.

74. Plaintiff was exposed to Defendant's deceptive Good Start Gentle advertising materials beginning in 2012 and continuing until 2014. Among other things, Plaintiff saw and relied on the tamper-evident seal displayed in Exhibit B, the television commercial shown in Exhibit D, and the magazine advertisement shown in Exhibit E.

75. Based on Defendant's false and misleading claims that Good Start Gentle reduced the risk of developing allergies, atopic dermatitis, and was endorsed or certified by the FDA, Plaintiff routinely purchased Good Start Gentle formula to feed her nieces and nephews—rather than competitor infant formulas—beginning in 2012 until the early part of 2014.

76. Plaintiff purchased Good Start Gentle infant formula in various containers and formats (i.e. powder and ready-to-feed), including plastic containers with the misleading tamper-evident seal: "1st & ONLY Routine Formula TO REDUCE RISK OF DEVELOPING ALLERGIES" as depicted in Exhibit B.

77. Plaintiff bought Gerber Good Start Gentle infant formula containers from stores located in or near Champaign, Illinois, including Target, Walmart, and a regional grocery chain, Meijers, for prices generally ranging between $20-50 (the higher prices being for multi-packs of Good Start Gentle formula).

78. Plaintiff would not have purchased Gerber Good Start Gentle—or would not have purchased it for the prices that she did—had she known (1) Good Start Gentle did not reduce the risk of allergies and atopic dermatitis, and (2) the FDA did not endorse, approve, or certify the health claims Defendant made on Good Start Gentle labels and advertising.

79. However, Plaintiff did not become aware of Defendant's deceptive advertising practices until late 2015 or early 2016 when she read news articles on the internet discussing the allegations against Defendant concerning Good Start Gentle. By that time, she no longer acted as caretaker for infants or purchased infant formula.

80. For these reasons, Plaintiff and other Class members incurred damages from Defendant's misconduct.

CLASS ACTION ALLEGATIONS

81. Plaintiff asserts her claims on behalf of the following proposed Class:

> All persons who have purchased Gerber Good Start Gentle infant formula in Illinois during the applicable statute of limitations. The Class excludes any judge or magistrate assigned to this case, Defendant and any entity in which Defendant has a controlling interest, and its officers, directors, legal representatives, successors and assigns. Also excluded from the class are those who purchased Gerber Good Start Gentle infant formula for the purpose of resale and those who assert claims for personal injury.

82. Numerosity: The Class is so numerous that joinder of all Class members is impracticable. The Class includes hundreds, and likely thousands, of Defendant's customers.

83. Typicality: Plaintiff's claims are typical of the members of the Proposed Class

because, like the other Class members, she was exposed to Defendant's deceptive advertising and business practices and purchased Good Start Gentle based on that advertising.

84. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class, and has retained counsel experienced in complex class action litigation. Plaintiff has no interests which are adverse to those of the Class that she seeks to represent.

85. Commonality: Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including:

a) Whether Defendant falsely advertised Good Start Gentle as a product endorsed by the FDA to reduce the occurrence of allergies and atopic dermatitis in infants;

b) Whether Defendant disseminated misleading labels, commercials, print advertisement, point-of-sale displays, and other promotional materials in an effort to convince customers to purchase Good Start Gentle based on false representations – namely that the FDA issued a qualified health claim that Good Start Gentle reduced the occurrence of infant allergies;

c) Whether Defendant used the term "qualified health claim" in order to mislead consumers into believing that the FDA certified the quality of Good Start Gentle or that Good Start Gentle was fit for a particular purpose, rather than convey that any potential health claim was limited, restricted, or insufficient;

d) Whether Defendant violated the Illinois Consumer Fraud and Deceptive Trade Practices Act;

e) Whether Defendant breached Good Start Gentle's express warranty;

f) Whether Defendant intentionally misrepresented the health benefits and FDA endorsement of Good Start Gentle;

g) Whether Plaintiff and the Class are entitled to actual, statutory, and punitive damages; and

h) Whether Plaintiff and the Class are entitled to restitution.

86. These and other questions of law and fact are common to the Class and predominate over any questions affecting only individual members of the Class.

87. Plaintiff cannot be certain of the form and manner of proposed notice to class members until the class is finally defined and discovery is completed regarding the identity of class members. Plaintiff anticipates, however, that notice by mail will be given to class members who can be identified specifically. In addition, notice may be published in appropriate publications, on the internet, in press releases and in similar communications in a way that is targeted to reach those who may have purchased Gerber Good Start Gentle infant formula. The cost of notice, after class certification, trial, or settlement before trial, should be borne by Defendant.

88. Class action status is warranted under Rule 23(b)(1)(A) because the prosecution of separate actions by or against individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendant.

89. Class action status is also warranted under Rule 23(b)(1)(B) because the prosecution of separate actions by or against individual members of the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications, or substantially impair or impede their ability to protect their interests.

90. Class action status is also warranted under Rule 23(b)(3) because questions of law or fact common to the members of the Class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

91. Plaintiff reserves her right to modify or amend the definition of the proposed Class at any time before the Class is certified by the Court.

FIRST CLAIM FOR RELIEF

Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act

(815 ILCS § 505/1, *et seq.*)

92. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

93. Plaintiff brings this claim on behalf of herself and the proposed Class.

94. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815ILCS §§ 505/1, *et seq.*, provides protection to consumers by mandating fair competition in commercial markets for goods and services.

95. The ICFA prohibits any deceptive, unlawful, unfair, or fraudulent business acts or practices including using deception, fraud, false pretenses, false promises, false advertising, misrepresentation, or the concealment, suppression, or omission of any material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act." 815 ILCS § 505/2.

96. Defendant is a "person" as defined by section 505/1(c) of the ICFA.

97. The Plaintiff and each member of the Class are "consumers" as defined by section 505/1(e) of the ICFA.

98. Defendant's marketing of Good Start Gentle created a likelihood of deception or had the capacity to deceive Plaintiff, other members of the Class, and consumers at large. Defendant falsely and misleadingly represented that Good Start Gentle had the ability to reduce the risk of developing allergies, atopic dermatitis, and was specially endorsed or certified by the FDA. Defendant violated the ICFA when it misrepresented and omitted facts regarding the true benefits attributes, and sponsorship of Good Start Gentle infant formula.

99. Moreover, by falsely and misleadingly advertising and labeling Good Start Gentle as the first and only formula which reduced the risk of allergies and atopic dermatitis, and as a formula uniquely endorsed by the FDA, Defendant used or employed practices violating section 510/2 of the Uniform Deceptive Trade Practices Act ("DTPA"), including:

- 510/2(a)(2) which proscribes causing a "likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;"
- 510/2(a)(3) which proscribes causing a "likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another;"
- 510/2(a)(5) which proscribes "represent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have"
- 510(a)(7) which proscribes "represent[ing] that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another;"

- 510(a)(9) which proscribes "advertis[ing] goods or services with intent not to sell them as advertised."

100. Good Start Gentle constitutes "merchandise" under the meaning of section 505/1(b) of the IFCA and its sale is within the meaning of "trade" or "commerce" under the section 505/1(f) of the IFCA, which encompasses the "advertising, offering for sale, sale, or distribution of any services and distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of [Illinois]."

101. Defendant intended that Plaintiff, the Class, and other consumers rely on its false and misleading representations in order to increase sales and the selling price of Good Start Gentle.

102. In turn, Plaintiff and members of the Class relied upon Defendant's misrepresentations and omissions when they purchased Good Start Gentle.

103. If Plaintiff and the Class had been aware of Good Start Gentle's true benefits, attributes, and sponsorship, they would not have purchased Good Start Gentle, or would have only purchased Good Start Gentle for a much lower price.

104. For these reasons, and for reasons stated elsewhere in the Complaint, Plaintiff and the Class suffered actual damages proximately caused by Defendant.

SECOND CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

105. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

106. Plaintiff brings this claim on behalf of herself and the proposed Class.

107. As set forth hereinabove, Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and through other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. That affirmation of fact and/or promise became part of the basis of the bargain between the parties and thus constituted an express warranty.

108. Thereon, Defendant sold the goods to Plaintiff and the Class, who bought the goods from Defendant.

109. However, Defendant breached the express warranty in that the goods were in fact not FDA approved, did not comply with the FDA's limited qualified health claim language requirements, and do not reduce the risk of allergies or atopic dermatitis in infants. As a result of this breach, Plaintiff and the Class in fact did not receive goods as warranted by Defendant.

110. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

FRAUDULENT MISREPRESENTATION

111. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

112. Plaintiff brings this claim on behalf of herself and the proposed Class.

113. As set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce

the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

114. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies or atopic dermatitis in infants.

115. Defendant made these misrepresentations with actual knowledge of their falsity.

116. Defendant made the misrepresentations herein alleged with the intention of inducing the public to purchase Defendant's products.

117. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

118. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Good Start Gentle infant formula.

119. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the Class, prays for relief as follows:

a) Determining that this action may proceed as a class action under Rule 23 of the Federal Rules of Civil Procedure;

b) Designating Plaintiff as the Class representative;

c) Designating Plaintiff's counsel as counsel for the Class;

d) Issuing proper notice to the Class at Defendant's expense;

e) Awarding restitution and disgorgement of Defendant's revenues obtained by means of any wrongful act or practice to Plaintiff and Class members;

f) Awarding actual, statutory, and punitive damages and interest to Plaintiff and Class members;

g) Awarding reasonable attorneys' fees, interest, and costs to the full extent permitted by law; and

h) All such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff and the Class demand a trial by jury.

Dated: May 10, 2017

Respectfully submitted,

By:/s/ Edward A. Wallace
Edward A. Wallace
Adam Prom
WEXLER WALLACE LLP
55 W. Monroe St. #3300
Chicago, IL 60603
Telephone: 312-346-2222
Fascimile: 312-346-0022
Email: eaw@wexlerwallace.com
Email: ap@wexlerwallace.com

Stephen J. Fearon, Jr (subject to *pro hac vice)*
Paul V. Sweeny(subject to *pro hac vice*)
SQUITIERI & FEARON, LLP
32 East 57th St., 12th Floor
New York, New NY 10022
Telephone: (212) 421-6492
Facsimile: (212) 421-6553
Email: stephen@sfclasslaw.com
Email: paul@sfclasslaw.com

Daniel Keller (subject to *pro hac vice*)
Dan C. Bolton (subject to *pro hac vice*)
KELLER, FISHBACK & JACKSON LLP

28720 Canwood Street, Suite 200
Agoura Hills, CA 91301
Telephone: (818) 342-7442
Fascimile: (818) 342-7616
Email: dkeller@kfjlegal.com
Email: dbolton@kfjlegal.com

Attorneys for Plaintiff and the Proposed Class